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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,049	07/30/2004	Bernd Stahl	STAH3008/REF	2144

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	**PAPER NUMBER**
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,049	STAHL ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Preliminary Amendment of 7/30/2004 presents claims 1-13 for prosecution.

Specification

The abstract of the disclosure is objected to because in formula II the substitution X appears at the wrong place. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the carbohydrate of formula I, does not reasonably provide enablement for a composition comprising the carbohydrate of formula I and further carbohydrates which are different, active agents(s), ingredients, auxiliaries, moisturizing agents, thickening agents, flavoring agents sweetening agents and carriers, method of treatment and prevention of immunomodulation, immunosuppression and infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims
(B) The state of the prior art
(C) The level of predictability in the art
(D) The amount of direction provided by the inventor
(E) The existence of working examples
(F) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claim 10 is drawn to a composition of claim 1 and claim 13 is drawn to a sialyzed carbohydrate of formula I, both of which are for prevention. The scope of the claim is seen to include the administration of the said composition to a healthy subject, wherein the said compound/composition prevents said disease from manifesting itself in the

subject. Claim 11 recites the broad terms further carbohydrates which are different, active agents(s), ingredients, auxiliaries, moisturizing agents, thickening agents, flavoring agents sweetening agents and carriers. These broad terms are seen to include several compounds, both known and unknown at the time of filing. Claim 12 is drawn to a method of immunomodulation, immunosuppression and treatment of infections using the carbohydrate of formula I or composition of claim 10. The recitation, "infections" is seen as including any type of infection.

The state of the prior art

The examiner notes that WO 00/46379 (cited by applicants) teaches sialized carbohydrates and compositions comprising them. However, there is no disclosure of potential immunomodulation, immunosuppression and treatment and prevention of any infection using the compounds/compositions seen in the prior art. The prior art appears to be silent with regard to preventive procedures recognized by skilled artisans in the field.

The level of predictability in the art

The examiner acknowledges the probability that administration of the said compounds/compositions may have a reasonable expectation of success for the said treatment and prevention as instantly claimed. There is not seen sufficient data to substantiate the assertion that the infections/conditions may be prevented by the use of the composition and compounds as instantly claimed. According to The Merck Index (1992, pages 279-303) the immune system and its response is complicated and involves genetic factors too.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427.2d 833, 166 USPQ (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since on of skill in the art cannot fully visualize or recognize the identity of the members of the genus. In the absence of fully recognizing the identity of the members of the genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having the claimed functional properties in the compositions herein. Goodman and Gilman's "The Pharmacological Basis of Therapeutics", 10th Ed., 1996, page 54, teaches that the frequency of significant beneficial or adverse drug interactions is unknown (bottom of the left column at page 54). Relatively small changes in the drug level can have significant adverse consequences. In the instant case one of skill in the art would not be able to fully predict possible adverse interactions occurring with the many combinations of any compounds having the functional properties in the pharmaceutical compositions claimed herein. Thus, the teachings of Gillman and Goodman clearly support that the instantly claimed invention is highly unpredictable.

The amount of direction provided by the inventor

The instant specification is not seen to provide sufficient guidance that would allow a skilled artisan to extrapolate from the disclosure and the limited examples provided to enable the use of the active agents and compositions to enable the treatment and prevention as instantly claimed. The specification also fails to direct the skilled

artisan to correlative prior art disclosures which teach procedures which might provide the basis for an advance in treating infections which encompasses prevention.

The existence of working examples

The working examples set forth in the instant specification are drawn to food and beverages comprising the carbohydrates of formula I. The skilled artisan in this field would not extrapolate the treatment and preventive efficacy of the composition claimed or the use of the same in preventive methods from the limited example provided. There are no working examples that show the treatment of infection, immunomodulation or immunosuppression using the compounds/compositions of the instant invention.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the treatment of infection, immunomodulation or immunosuppression with the compounds and compositions and method set forth in the claims. One of ordinary skill in the art would have to perform undue experimentation to find out which combinations of the sialyzed carbohydrates and the other agents give stable compositions and their treatment, preventive, immunomodulating and immunosuppresing activities.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 provide for the use of sialyzed carbohydrates, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The term "several" in claims 1, 11 and 13 is a relative term which renders the claims indefinite. The term "several" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 11 recites the terms, "further active agent(s), such ingredients", without a definition. In the absence of the specific names or chemical structure, the identity of the said agents and ingredients would be difficult to describe and the metes and bounds of said agents and ingredients applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Claim 12 recites, "in such an amount" and further recites, "at least 1mg of formula I per kg of body weight". It is not clear what applicants intend by the said recitations. The recitation, "at least" indicates that more than the recited amount may be used. Since 1mg is the lower limit, the upper limit is not defined. This renders the claim indefinite. A similar recitation is also seen in claim 6.

Claim 13 is drawn to a carbohydrate of general formula I having at least one carbohydrate unit of general formula II. The first formula recited is labeled (I) and (II) and a second formula labeled (II) is also recited. Formula (II) recited in the latter half of

the claim has a subscript n, which has not been defined other than reciting that n is the number of carbohydrate units. The definition of n as 1 to 50 earlier in the claim is seen as the definition for the n appearing in the first formula. In the absence of the definition of n in the second formula the claim is rendered indefinite. In the absence of a definition for n in the second formula the claim is being examined as being drawn to a carbohydrate containing formula (II) wherein n is any integer including zero. This lack of clarity and indefiniteness is also seen in the recitation of claim 1.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 10 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 7 of copending Application No. 10/148,193('193 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 10 is drawn to a food, dietetic or pharmaceutical composition comprising a polysaccharide that is composed of a sialic acid or sialic acid derivative, N-acetylated glucosamine or N-acetylated galactosamine, glucose and galactose.

Claims 1, 3 and 7 of copending '193 application are also drawn to the same type of compositions comprising of the same monomeric carbohydrate units.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that there is substantial overlap between instant claim 10 and claims 1, 3 and 7 of the copending '913 application. Similarity in structure, function and utility entails motivation for making such a composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 10 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6 and 9-10 of U.S. Patent No. 6,576,251 ('251 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 10 is drawn to a food, dietetic or pharmaceutical composition comprising a polysaccharide that is composed of a sialic acid or sialic acid derivative, N-acetylated glucosamine or N-acetylated galactosamine, glucose and galactose.

Claims 1, 6 and 9-10 of the '251 patent are also drawn to the same type of compositions comprising of the same monomeric carbohydrate units.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that there is substantial overlap between instant claim 10 and claims 1, 3 and 7 of the copending '913 application. Similarity in structure, function and utility entails motivation for making such a composition.

Conclusion

Claims 1-13 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

1/09/07

Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623